



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	PLICATION OF: Smoliarov, at al.	)	) GROUP ART UNIT: 3762					
SERIAL N	NUMBER: 09/717,559	j :	EXAMINER:					
FILED: N	Safety Mechanisms to Prevent Accidental Patient Injection and Methods of Same	) ) ) )	CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" mailing label number: EV 113373485 US Date of Deposit: December 20, 2002 I hereby certify that these papers or fees are being delivered to the U.S. Patent and Trademark Office, Washington, DC 20231  Tim Hubalik (typed or printed name of person delivering paper or fee)					
			(signature of person delivering paper or fee)					

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. §1.97(B)

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DEC 2 4 2002

Assistant Commissioner for Patents Washington, DC 20231

**TECHNOLOGY CENTER R3700** 

#### Dear Examiner:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants hereby submit the documents listed on the attached PTO 1449 for consideration by the Examiner. These documents have been submitted before the mailing of the first Office Action. A copy of the listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents. Applicants request that the Examiner: (1) initial each reference listed on the enclosed Form PTO 1449 indicating that the Examiner has considered and made those references of record in this application, and (2) return a copy of the initialed Form PTO 1449 to Applicants.

This submission does not represent that a search has been made or that no better art exists, and does not constitute an admission that the listed documents are material or constitute

"prior art" under Rule 1.56. If it should be determined that any listed document does not constitute "prior art" under United States law, we reserve the right to present to the PTO relevant facts and law regarding the appropriate status of such document. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed document, should the document be applied against the claims of the present application.

Under 37 CFR § 1.97(b), Applicants believe no fee is due with this submission. However, if there are any fees due in connection with the filing of this statement, please charge the fee to our Deposit Account No. 13-0019.

By: MAYER, BROWN, ROWE & MAW

By: Christine M. Rebman (Reg. No. 50,546)

Dated: December 20, 2002

MAYER, BROWN, ROWE & MAW P.O. Box 2828 Chicago, IL 60609-2828 (312) 701-7174 Customer No. 26565

DATE: December 20, 2002

SHEET 1 of 3

PTO - 1449 (Modified)

FO FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. SERIAL NO. 09/717,559

01752810 **APPLICANT** 

B. Smolyarov, et al.

FILING DATE GROUP

November 21, 2000

3762

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98 (b))

## **U.S. PATENT DOCUMENTS**

EXAMINER	TAB		D 4 7		~ .	11 18 4			ISSUE	DATENTEE	01.400	SUB	FILING
INITIAL	TAB	3	0	5	1 N	3	BEI	₹   9	DATE 10/09/62	PATENTEE Ismach	CLASS	CLASS	DATE
	1.	3	2	9	2	6	2	2	12/20/66	Banker			
	2.	3	4	6	1	8		7	08/19/69	Zimmet, et al.	RE	CEIV	
		3	5	1	5	1	3	0	06/02/70	Tsujino			
	4.	3	5	1	8	<b>-</b>	9	0	07/07/70	Banker	+ DE(	2 4 20	N2
	5.	3	7	L	-	9	1	ļ -	L			- 1 20	٥٤
	6.	4	<u> </u>	8	8		8	5	01/29/74	Laurens	TECHNOLO	GY CENT	FR 83700
	7.		1	0	3	6		4		Ismach		- 02,111	-11110700
	8.	4	1	2	4	0	2	4	11/07/78	Schwebel, et al.			· · · · · · · · · · · · · · · · · · ·
	9.	4	1	6	5	7	3	9	08/28/79	Doherty, et al.			
	10.	4	2	6	6	5	4	1	05/12/81	Landau	ļ		
	11.	4	4	0	3	9	8	6	09/13/83	Dettbarn, et al.			
	12.	4	5	9	6	5	5	6	06/24/86	Morrow, et al.			
	13.	4	7	2	2	7	2	8	02/02/88	Dixon			
	14.	4	8	5	0	9	6	7	07/25/90	Cosmai			
	15.	4	8	7	4	3	6	7	10/17/89	Edwards			
	16.	4	9	1	3	6	9	9	04/03/90	Parsons			
	17	5	0	4	9	1	2	5	09/17/91	Accaries, et al.			
	18.	5	0	6	2	8	3	0	11/05/91	Dunlap			
	19.	5	0	6	3	9	0	5	11/12/91	Farrell			
	20.	5	2	5	6	1	4	2	10/26/93	Colavecchio			
	21.	5	3	1	2	3	3	5	05/17/94	McKinnon, et al.			
	22.	5	3	9	9	1	6	3	03/21/95	Peterson, et al.			
	23.	5	5	0	1	6	6	6	03/26/96	Spielberg			
	24.	5	5	0	3	6	2	7	04/02/96	McKinnon, et al.			
	25.	5	5	2	0	6	3	9	05/28/96	Peterson, et al.			
	26.	5	5	3	6	2	4	9	07/16/96	Castellano, et al.			
	27.	5	5	6	9	1	8	9	10/29/96	Parsons			- · · · · · · · · · · · · · · · · · · ·
	28.	5	5	9	3	3	9	0	01/14/97	Castellano, et al.			
	29.	5	5	9	9	3	0	2	02/04/97	Lilley, et al.			
	30.	5	7	0	4	9	1	1	01/06/98	Parsons	1		

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE: December 20, 2002 SHEET 2 of 3

TO - 1449 (Modified)

31.

ORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (Modified)

ATTY. DOCKET NO. SERIAL NO. 01752810 09/717,559

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

B. Smolyarov, et al.

Castellano, et al.

**APPLICANT** 

GROUP **FILING DATE** 

November 21, 2000

3762

(37 CFR 1.98 (b))

#### **U.S. PATENT DOCUMENTS**

03/17/98

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32.	5	/	3	10	/	2	3	03/24/98	Castellano, et al.	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
 33.	5	7	4	6	7	1	4	05/05/98	Salo, et al.	TECHNOLOGY CENTER R370
34.	5	7	8	2	8	0	2	07/21/98	Landau	THOUSANDER H37
35.	5	8	0	0	3	8	8	09/01/98	Schiff, et al.	
 36.	5	8	4	6	2	3	3	12/08/98	Lilley, et al.	
37.	5	8	5	8	0	0	1	01/12/99	Tsals, et al.	
38.	5	8	6	5	7	9	5	02/02/99	Schiff, et al.	
39.	5	8	6	5	7	9	6	02/02/99	McCabe	
 40.	6	0	5	3	8	8	9	04/25/00	Heinzen, et al.	
41.	6	0	8	3	1	9	7	07/04/00	Umbaugh	
 42.	6	1	0	2	8	9	6	08/15/00	Roser	
 43.	6	1	3	5	9	7	9	10/24/00	Weston	

#### FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

	TAB	B DOCUMENT NUMBER						R	PUB DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION
	4.4	12	6	2	9	3	I 4	8				CLASS	LATION
	44.	2	6	<u> </u>	19	3	4	<u> </u>	10/06/89	FR w/English Translation			
	45.	2	6	4	1	1	9	0	07/06/90	FR w/English Translation			
	46.	0	1	0	6	0	7_	8	02/26/93	RO w/English Translation			
	47.	0	1	0	8	1	5	0	02/28/94	RO w/English Translation			
	48.	2	0	0	8	9	3	2	03/15/94	RU w/English Abstract			
	49.	2	1	0	8	1	1	7	04/10/98	RU w/English Abstract			
	50.	0	2	5	7	6	9	7	11/20/69	SU w/English Translation			
	51.	0	3	7	3	0	0	5	03/29/73	SU w/English Translation			
	52.	0	7	1	8	1	1	1	02/28/80	SU w/English Abstract			
	53.	1	2	7	9	6	3	6	12/30/86	SU w/English Abstract			
	54.	9	7	3	4	6	5	2	09/25/97	WO A1			
	55.	9	8	1	3	4	7	0	04/02/98	WO A1			
	56.	9	9	0	1	1	6	8	01/14/99	WO A1			
	57.	9	9	0	1	1	6	9	01/14/99	WO A1			
	58.	9	9	0	3	5	2	9	01/28/99	WO A2			
	59.	0	5	2	6	7	7	2	02/10/93	EP A1			
VANHED	•——									DATE CONSIDERED			

**EXAMINER** 

DATE CONSIDERED

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DATE: December 20, 2002

SHEET 3 of 3

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO	•	
	01752810	09/717,559		
INFORMATION DISCLOSURE	APPLICANT			
STATEMENT BY APPLICANT	B. Smolyarov, et al.		RECEIN	F
(Use several sheets if necessary)	FILING DATE	GROUP	ILOLIV	
(Use several sheets if necessary)	November 21, 2000	3762	DEC 2 4 2	<b>ກ</b> ກ2
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 60.	0	7	7	6	2	2	4	12/09/98	EP B1
 61.	0	7	8	8	3	8	6	01/13/99	EP B1
62.	0	7	9	9	0	6	4	08/25/99	EP B1
63.	0	8	8	8	7	9	0	01/07/99	EP A1
 64.	0	8	8	8	7	9	1	01/07/99	EP A1
 65.	0	9	5	1	9	1	7	10/27/99	EP A2

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	66.	Cool.Click: A Needle-Free Device For Growth Hormone Delivery, The Medical
·		Letter, Vol. 43, No. 1095, pp. 2-3 (January 8, 2001).
	67.	Figge, et al., Anatomic Evaluation of a Jet Injection Instrument Designed to
		Minimize Pain and Inconvenience of Parental Therapy, The American
		Practitioner, Vol. 3, No. 4, pp. 197-206 (December 1948).
	68.	Brochure on Agro-Jet: Needle-Less Jet Injector by M.I.T.
	69.	Description and Operating Instructions for Hydraulic Needleless Injector by V/O
		Medexport in Moscow.
	70.	Dimache, et al., A Clinical, Epidemiological and Laboratory Study on Avoiding
		the Risk of Transmitting Viral Hepatitis During Vaccinations with the Dermojet
		Protected by an Anticontaminant Disposable Device, Vaccine, Vol. 15, No. 8,
		pp. 1010-13 (1997).
	71.	Jet Gun Injection Transmission: A Clinical, Epidemiological and Laboratory
		Study on Avoiding the Risk of Transmitting Viral Hepatitis During Vaccinations
}		with the Dermojet Protected by an Anticontaminant Disposable Device,
		American Journal of Infection Control, Vol. 26, No. 4, pp. 442-5 (August 1998).
EXAMINER	•	DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## 12-23-02.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. F	Patent Application of:	)		CERTIFICATE OF MAILING BY "EXPRESS
	B. Smolyarov, et al.	)		MAIL" "Express Mail" mailing label number EV 113373485 US
Serial No.:	09/717,559	)	Examiner:	Date of Deposit: December 20, 2002 I hereby certify that this paper or fee is being deposited with the United States Postal Service
Filed:	November 21, 2000	)	Group Art Unit: 3762	"Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to U.S. Patent and Trademark Office,
For:	Safety Mechanisms to Prevent Accidental Patient Injection and Methods of Same	) ) )		Washington, DC 20231  Tim Hubalik (typed or primed name of person mailing paper or fee) (signature of person mailing paper or fee)

## TRANSMITTAL LETTER

Assistant Commissioner for Patents Washington, DC 20231

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Dear Sir:

**TECHNOLOGY CENTER R3700** 

Enclosed herewith is the following for the above-captioned case:

- 1. Supplemental Information Disclosure Statement;
- 2. 1449 Form and (71) references;
- 3. Associate Power of Attorney; and
- 4. Return Receipt Card.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019.

Respectfully submitted,

MAYER, BROWN, ROWE & MAW

By: Christine M. Rebman (Reg. No. 50,546)

Dated: December 20, 2002

MAYER, BROWN, ROWE & MAW P.O. Box 2828 Chicago, IL 60609-2828 (312) 701-7174 Customer No. 26565